IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Garvey et al**

Serial No.: **Not Yet Assigned**

Filing Date: **December 21, 2001**

Title: **Nitrosated and Nitrosylated Alpha-Adrenergic Receptor Antagonist Compounds, Compositions and Their Uses**

Docket Number: **102258.346 US2**

ATTN: BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, DC 20231

PRELIMINARY AMENDMENT

Prior to consideration of the above application on the merits, please enter the following amendment without prejudice.

IN THE CLAIMS:

Attached hereto as Appendix 1 is a copy of the pending claims. Attached hereto as Appendix 2 is a copy of the amendments made to the claims.

I. Remarks

After entry of the preliminary amendment, claims 35-37 are pending in the application.

Claims 1-34 have been canceled, without prejudice.

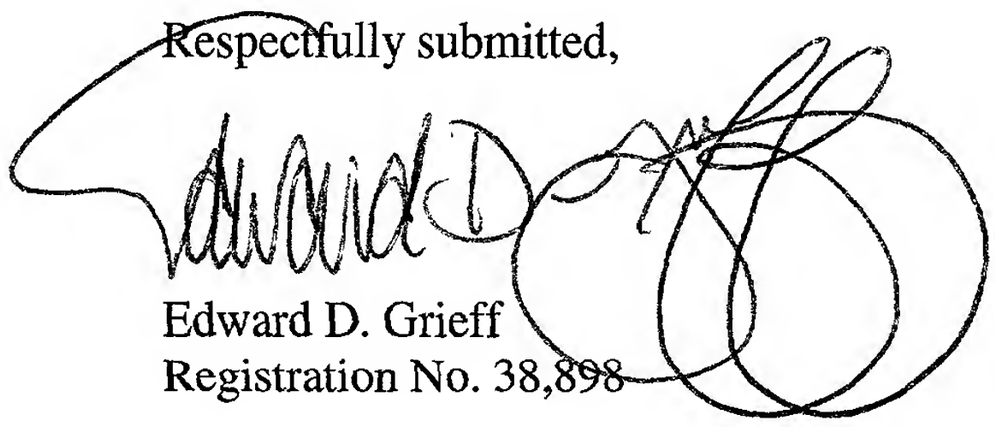
Added claim 35 is identical to claim 1 of U.S. Patent No. 6,165,975, issued on December 26, 2000. Pursuant to 37 CFR § 1.606 and § 1.607, Applicants request that an interference be declared with U.S. Patent No. 6,165,975.

Added claim 36 is identical to claim 1 of U.S. Patent No. 6,306,841, issued on October 23, 2001. Pursuant to 37 CFR § 1.606 and § 1.607, Applicants request that an interference be declared with U.S. Patent No. 6,306,841.

Added claim 37 is identical to claim 1 of U.S. Patent No. 6,013,002, issued on February 29, 2000. Pursuant to 37 CFR § 1.606 and § 1.607, Applicants request that an interference be declared with U.S. Patent No. 6,013,002.

No issues of new matter should arise and entry of the amendment is respectfully requested.

Respectfully submitted,



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Appendix 1 – Pending Claims

35. (New) A method of treatment, in an organism, of a vascular condition, comprising administration of at least one agent at a level which enhances NO and which does not appreciably alter normal systemic vascular tone in said organism.

36. (New) A method for treating sexual dysfunction in a female individual, comprising administering to the vagina, vulvar area and/or urethra of the individual a pharmaceutical formulation that comprises an effective amount of a nitrovasodilator selected from the group consisting of sodium nitroprusside, diazenium diolates, molsidomine, linsidomine chlorohydrate, S-nitrosothiols, organic nitrates, pharmacologically acceptable salts, esters, analogs, derivatives, prodrugs and inclusion complexes of any of the foregoing, and combinations thereof.

37. (New) A method of enhancing sexuality in a female having a clitoris comprising the step of topically administering to a surface of the clitoris a composition whose primary agent is a vasodilator and whose secondary agent is a carrier in which the vasodilator is dispersed to deliver it directly to said surface so that it is retained and absorbed thereby, said composition being in a formulation and in a dosage which is substantially free of toxicity and therefore does not give rise to an adverse reaction.

Appendix 2 – Amendments to Claims

Cancel claims 1-34, without prejudice.

35. (New) A method of treatment, in an organism, of a vascular condition, comprising administration of at least one agent at a level which enhances NO and which does not appreciably alter normal systemic vascular tone in said organism.

36. (New) A method for treating sexual dysfunction in a female individual, comprising administering to the vagina, vulvar area and/or urethra of the individual a pharmaceutical formulation that comprises an effective amount of a nitrovasodilator selected from the group consisting of sodium nitroprusside, diazenium diolates, molsidomine, linsidomine chlorohydrate, S-nitrosothiols, organic nitrates, pharmacologically acceptable salts, esters, analogs, derivatives, prodrugs and inclusion complexes of any of the foregoing, and combinations thereof.

37. (New) A method of enhancing sexuality in a female having a clitoris comprising the step of topically administering to a surface of the clitoris a composition whose primary agent is a vasodilator and whose secondary agent is a carrier in which the vasodilator is dispersed to deliver it directly to said surface so that it is retained and absorbed thereby, said composition being in a formulation and in a dosage which is substantially free of toxicity and therefore does not give rise to an adverse reaction.